



PATENT
Customer No. 22,852
Attorney Docket No. 06530.0318

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John A. GRIEGO et al.

Application No.: 10/727,626

Filed: December 5, 2003

For: MEDICAL DEVICE WITH
DEFLECTING SHAFT AND
RELATED METHODS OF
MANUFACTURE AND USE

Group Art Unit: 3739

Examiner: M. J. Kasztejna

Confirmation No.: 9106

Mail Stop PG PUB

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

**REQUEST FOR CORRECTED PATENT APPLICATION
PUBLICATION UNDER 37 C.F.R. § 1.221(b)**

The Office published the above-identified application, as Publication No. US 2005-0124912-A1, with a publication date of June 9, 2005. The published application contains a material mistake that is the fault of the Office. Attached hereto is a copy of the relevant pages of the originally filed application (pages 19-22) and a marked-up copy of the corresponding pages of the published application containing the mistake (pages 5 and 6).

The mistake, which is indicated in red ink on the relevant pages of the marked-up copy of the published application attached hereto, is as follows:

- In paragraph [0062], line 6, after "sleeve 75 may be coated," insert text from paragraph [0065], line 3 (after "assembly 60 may"), through paragraph [0068], line 6 (before "include two").

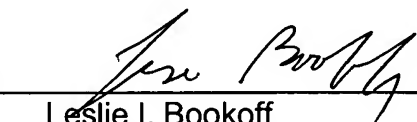
This mistake may create ambiguities, affecting the public's ability to appreciate the technical disclosure of the application publication or to determine the scope of the provisional rights that Applicants may later seek to enforce. See 37 C.F.R. § 1.221(b). For at least this reason, Applicants request that the Office correct the above-identified mistake in the published application.

Applicant believes that no fee is due in connection with this Request. If, however, any Petition or fee is due, please grant the Petition and charge the fee to our Deposit Account no. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON,
FARABOW, GARRETT & DUNNER, L.L.P.

Dated: July 12, 2005

By: 
Leslie I. Bookoff
Reg. No. 38,084

931992.1

locked in place by a suitable mechanism. For example, the bore 69a may have a stepped configuration with varying diameter, where a locking coil may be disposed against a larger diameter area and threadedly engage with the wire coil 45 to secure the wire coil 45 to the handle assembly 60.

[0059] As also shown in Fig. 1, the device 10 includes a control member 70, such as, for example, a single-filament or multi-filament shaft or wire, used for manipulating the end effector assembly 20 from the handle assembly 60. The control member 70 may be flexible enough to pass through a tortuous body cavity, yet sufficiently stiff to resist minor compressive force, thereby permitting axial movement of the control member 70 relative to the control shaft 40. To aid this purpose, the device 10 may optionally include an inner sleeve 75 (see Fig. 3), such as, for example, FEP sheath, extending from the distal end of the wire coil 45 therethrough into the distal shaft 69 of the handle assembly 60. Alternatively, or in addition, this inner sleeve 75 may act as a bearing member between the control member 70 and the lumen of the control shaft 40. The sleeve 75 may be formed of a plastic material, such as, for example, PTFE, Nylon, Pebax, PP, or PE. If the control member 70 is formed of multi-filament shafts or wires, each individual shaft or wire may be covered with the sleeve material.

[0060] In an exemplary embodiment, the control member 70 may be made of stainless steel, nickel-titanium alloy, or a combination of the two, but any other suitable material known in the art may also be used. In another exemplary embodiment, at least a portion of the control member 70 or sleeve 75 may be coated

with a lubricating material, such as, for example, liquid silicon, to facilitate the axial movement of the control member 70.

[0061] As shown in Figs. 3 and 4, the distal end of each control member 70 may connect to the tang 29 of each jaw 22. The distalmost end of the control members 70 may include a first bent portion 78 which may extend through a bore 78a in the tang 29 and a second bent portion 79 which may be rotatably disposed in the recess 29a of the tang 29. The first bent portion 78 may form an approximately 90° bend with respect to the main portion of the control member 70. The control member 70 may have a reflex curve 77, to aid opening of the jaws 22 when the spool 67 is moved distally.

[0062] As shown in Fig. 1, the handle assembly 60 may include a thumb ring 61 fixedly attached to a main body 65, and a spool 67 slidably coupled to the main body 65, for manipulation of the end effector assembly 20. The spool 67 may be reciprocally slidable along the main body 65 so as to move the control member 70 coupled to the spool 67 relative to the control shaft 40. The spool 67 may be configured to rotate with respect to the axis of the main body 65 so as to control the orientation of the end effector assembly 20. As will be described herein, the reciprocal movement of the spool 67 may control the operation of the end effector assembly 20 as well as the deflection of the distal portion of the control shaft 40.

[0063] The handle assembly 60 may include the distal shaft 69, to which the proximal end of the control shaft 40 may be secured via a suitable locking member. Optionally, the distal shaft 69 may include a strain relief sheath (not shown) over the wire coil 45, which may extend slightly distally from the distal end of the distal shaft

69, in order to limit twist and movement of the wire coil 45 with the bore of the distal shaft 69 while preventing a sharp bend of the wire coil 45 at the distal end of the handle assembly 60.

[0064] As will be described herein, the proximal end of the control member 70, such as, for example, one or more pull wires, may extend through the control shaft 40 and the distal shaft 69, and fixedly secure to the movable spool 67 via a suitable connecting means, such as, for example, a crimp ring or a cross pin. In the embodiment shown in Fig. 1, the end of a cross pin 63 mates with a slot 62 in the spool 67 so as to lock the cross pin 63 therewith. The proximal ends of the pull wires 70 may then be locked into the cross pin 63 by a set screw 64, so that movement of the spool 67 may thereby effectuate movement of the pull wires 70, the distal ends of which are connected to the end effector assembly 20, as shown in Figs. 3 and 4.

[0065] In an application where mono-polar electric current needs to be supplied to the end effector assembly 20, the handle assembly 60 may include a suitable current supplier, such as an active cord connector, that may contact the control member 70. The control member 70 may then act as an electrical conductor to supply the current received from the current supplier to the end effector assembly 20. In an embodiment, the set screw 64 may be replaced by a suitable active cord connector that may contact the control member 70 and supply the electrical current therethrough to the end effector assembly 20.

[0066] In an application that may require bi-polar current, the two control members 70 may be insulated from each other, and the handle assembly 60 may

include two separate active cord connectors each contacting the respective one of the two control members 70, so that supplied bi-polar current may be applied across the jaws 22 of the end effector assembly 20. As mentioned above, the distal end of each control member 70 may be connected to the tang 29 of each jaw 22 of the end effector assembly 20. Each jaw 22 may then be insulated from each other and the clevis pin 27 by a non-conductive material, so that the applied current may flow only when the jaws 22 are in contact with each other or through a mutually conducting medium.

[0067] With reference to Figs. 6 and 7, a control mechanism that may enable deflection of a distal portion 48 of the control shaft 40 so as to facilitate movement of the end effector assembly 20 will be described, according to an exemplary embodiment of the invention. As shown in Figs. 6 and 7, the distal portion 48 of the control shaft 40 may be configured to exhibit higher flexibility than that of the remaining portion of the control shaft 40. For example, the exemplary control shaft 40 shown in Figs. 6 and 7 may be formed of a wire coil 45, and the distal portion 48 of the wire coil 45 is formed by a wire 58 having a diameter, d , that is smaller than a diameter, D , of a wire 52 in the remaining portion of the wire coil 45. The inner diameter of the wire coil 45 may remain substantially the same throughout the length of the wire coil 45. In an exemplary embodiment, for example, the distal portion 48 of the wire coil 45 may have an outer diameter of approximately 0.072 inch (= 1.83 mm), an inner diameter of approximately 0.032 inch (= 0.81 mm), and a wire diameter of approximately 0.020 inch (= 0.51 mm), while the remaining portion of the wire coil 45 may have an outer diameter of approximately 0.080 inch (= 2.0 mm), an

enough to prevent lumen collapse when tension on the control member 70 is generated. For that purpose, the elongated control shaft 40, as shown in FIGS. 3 and 4, may be formed of a wire coil 45. The wire coil 45 may include a coating of suitable biocompatible material, such as, for example, PTFE, PP, PE, Nylon, Pebax, Polyimide, or any other materials known in the art, on the outer surface of the wire coil 45. If the wire coil 45 is used in an electro-active device, the coating may also act as an insulator. Alternatively, or in addition, the control shaft 40 may include a tubular sleeve member, made of a plastic material, such as, for example, Teflon, PTFE, or any other suitable material known in the art. The wire coil 45 may also include a radiopaque filler, such as, for example, barium sulfate or tantalum, to enhance visualization under fluoroscopy. In addition, the wire coil 45 may include a hydrophilic lubricious material or other suitable lubricating material to reduce friction. The dimensions of the control shaft 40 may vary depending upon the type of the end effector assembly being used and/or the type of procedure being performed. In an exemplary embodiment, the wire coil 45 may have inner and outer diameters of approximately 0.032 inch (≈ 0.81 mm) and 0.080 inch (≈ 2.0 mm), respectively, and a length of approximately 240 cm.

[0059] The distal end portion 49 of the control shaft 40, as best shown in FIGS. 3 and 4, may be flattened for ease of connection between the proximal portion 21 of the clevis member 24 and the distal end of the control shaft 40. In various exemplary embodiments, the distal end of the shaft 40 may be connected to the clevis member 24, with or without the flattened distal end portion 49, via interference-fit, crimping, soldering, welding, fusing, adhesive, or any other suitable connection mechanisms known in the art.

[0060] The proximal end 41 of the control shaft 40 may be fixedly secured to the handle assembly 60 via a suitable connection mechanism known in the art. In the exemplary embodiment shown in FIG. 1, the proximal end of the wire coil 45 extends into a bore 69a formed in a distal shaft 69 of the handle assembly 60 and is locked in place by a suitable mechanism. For example, the bore 69a may have a stepped configuration with varying diameter, where a locking coil may be disposed against a larger diameter area and threadedly engage with the wire coil 45 to secure the wire coil 45 to the handle assembly 60.

[0061] As also shown in FIG. 1, the device 10 includes a control member 70, such as, for example, a single-filament or multi-filament shaft or wire, used for manipulating the end effector assembly 20 from the handle assembly 60. The control member 70 may be flexible enough to pass through a tortuous body cavity, yet sufficiently stiff to resist minor compressive force, thereby permitting axial movement of the control member 70 relative to the control shaft 40. To aid this purpose, the device 10 may optionally include an inner sleeve 75 (see FIG. 3), such as, for example, FEP sheath, extending from the distal end of the wire coil 45 there-through into the distal shaft 69 of the handle assembly 60. Alternatively, or in addition, this inner sleeve 75 may act as a bearing member between the control member 70 and the lumen of the control shaft 40. The sleeve 75 may be formed of a plastic material, such as, for example, PTFE, Nylon, Pebax, PP, or PE. If the control member 70 is formed of multi-filament shafts or wires, each individual shaft or wire may be covered with the sleeve material.

[0062] In an exemplary embodiment, the control member 70 may be made of stainless steel, nickel-titanium alloy, or a combination of the two, but any other suitable material known in the art may also be used. In another exemplary embodiment, at least a portion of the control member 70 or sleeve 75 may be coated 69, in order to limit twist and movement of the wire coil 45 with the bore of the distal shaft 69 while preventing a sharp bend of the wire coil 45 at the distal end of the handle assembly 60.

[0063] As will be described herein, the proximal end of the control member 70, such as, for example, one or more pull wires, may extend through the control shaft 40 and the distal shaft 69, and fixedly secure to the movable spool 67 via a suitable connecting means, such as, for example, a crimp ring or a cross pin. In the embodiment shown in FIG. 1, the end of a cross pin 63 mates with a slot 62 in the spool 67 so as to lock the cross pin 63 therewith. The proximal ends of the pull wires 70 may then be locked into the cross pin 63 by a set screw 64, so that movement of the spool 67 may thereby effectuate movement of the pull wires 70, the distal ends of which are connected to the end effector assembly 20, as shown in FIGS. 3 and 4.

[0064] In an application where mono-polar electric current needs to be supplied to the end effector assembly 20, the handle assembly 60 may include a suitable current supplier, such as an active cord connector, that may contact the control member 70. The control member 70 may then act as an electrical conductor to supply the current received from the current supplier to the end effector assembly 20. In an embodiment, the set screw 64 may be replaced by a suitable active cord connector that may contact the control member 70 and supply the electrical current therethrough to the end effector assembly 20.

[0065] In an application that may require bi-polar current, the two control members 70 may be insulated from each other, and the handle assembly 60 may be with a lubricating material, such as, for example, liquid silicon, to facilitate the axial movement of the control member 70.

[0066] As shown in FIGS. 3 and 4, the distal end of each control member 70 may connect to the tang 29 of each jaw 22. The distalmost end of the control members 70 may include a first bent portion 78 which may extend through a bore 78a in the tang 29 and a second bent portion 79 which may be rotatably disposed in the recess 29a of the tang 29. The first bent portion 78 may form an approximately 90° bend with respect to the main portion of the control member 70. The control member 70 may have a reflex curve 77, to aid opening of the jaws 22 when the spool 67 is moved distally.

[0067] As shown in FIG. 1, the handle assembly 60 may include a thumb ring 61 fixedly attached to a main body 65, and a spool 67 slidably coupled to the main body 65, for manipulation of the end effector assembly 20. The spool 67 may be reciprocally slidable along the main body 65 so as to move the control member 70 coupled to the spool 67 relative to the control shaft 40. The spool 67 may be configured to rotate with respect to the axis of the main body 65 so as to control the orientation of the end effector assembly 20. As will be described herein, the reciprocal movement of the spool 67 may control the operation of the end effector assembly 20 as well as the deflection of the distal portion of the control shaft 40.

(cont'd)

[0068] The handle assembly 60 may include the distal shaft 69, to which the proximal end of the control shaft 40 may be secured via a suitable locking member. Optionally, the distal shaft 69 may include a strain relief sheath (not shown) over the wire coil 45, which may extend slightly distally from the distal end of the distal shaft. include two separate active cord connectors each contacting the respective one of the two control members 70, so that supplied bi-polar current may be applied across the jaws 22 of the end effector assembly 20. As mentioned above, the distal end of each control member 70 may be connected to the tang 29 of each jaw 22 of the end effector assembly 20. Each jaw 22 may then be insulated from each other and the clevis pin 27 by a non-conductive material, so that the applied current may flow only when the jaws 22 are in contact with each other or through a mutually conducting medium.

[0069] With reference to FIGS. 6 and 7, a control mechanism that may enable deflection of a distal portion 48 of the control shaft 40 so as to facilitate movement of the end effector assembly 20 will be described, according to an exemplary embodiment of the invention. As shown in FIGS. 6 and 7, the distal portion 48 of the control shaft 40 may be configured to exhibit higher flexibility than that of the remaining portion of the control shaft 40. For example, the exemplary control shaft 40 shown in FIGS. 6 and 7 may be formed of a wire coil 45, and the distal portion 48 of the wire coil 45 is formed by a wire 58 having a diameter, d , that is smaller than a diameter, D , of a wire 52 in the remaining portion of the wire coil 45. The inner diameter of the wire coil 45 may remain substantially the same throughout the length of the wire coil 45. In an exemplary embodiment, for example, the distal portion 48 of the wire coil 45 may have an outer diameter of approximately 0.072 inch (≈ 1.83 mm), an inner diameter of approximately 0.032 inch (≈ 0.81 mm), and a wire diameter of approximately 0.020 inch (≈ 0.51 mm), while the remaining portion of the wire coil 45 may have an outer diameter of approximately 0.080 inch (≈ 2.0 mm), an inner diameter of approximately 0.032 inch (≈ 0.81 mm), and a wire diameter of approximately 0.024 inch (≈ 0.70 mm). It is to be understood that varying the flexibility of the control shaft 40 may be applied to any portion of the control shaft 40, including the distal portion 48, as shown in this example.

[0070] As will be described in more detail herein, this enhanced flexibility in the distal portion 48 relative to the remaining portion of the control shaft 40 allows selective deflection of the distal portion 48, thereby enhancing the movement of the end effector assembly 20, as shown in FIG. 7. For example, the spool 67 of the handle assembly 60 may be advanced distally to fully open the end effector assembly 20, as shown in FIG. 15 and to be described in more detail further herein. Upon further advancement of the spool 67 in the distal direction, additional pressure may be exerted on the control member 70, and the distal portion 48 having the higher flexibility than the remaining portion of the control shaft 40 may begin to deflect, as shown in FIGS. 7 and 16. Depending on the desired degree of deflection, a physician operating the device 10 may readily control the deflection by appropriately adjusting the movement of the spool 67.

[0071] Alternatively or additionally, in accordance with another embodiment of the invention, the flexibility may be adjusted by utilizing a wire material that has different characteristics from the material characteristics of the wire

in the remaining portion. These material characteristics include, but are not limited to, tensile strength, shear strength, or ductility, so as to adjust the desired flexibility of the distal portion 48, with or without altering the wire diameter in the distal portion 48 of the control shaft 40.

[0072] In still another exemplary embodiment of the invention, the wire coil 45 may be provided with a deflection control member 71, such as, for example, a flexible shaft or wire, controlling the deflection of the distal portion 48, together with the control member 70, as shown in FIG. 8. In this exemplary embodiment, the handle assembly 60 may integrally or separately include a suitable deflection controller for the deflection control member 71. For example, as shown in FIGS. 1A, a deflection controller for the deflection control member 71 may be provided as an additional spool 667b integrally formed in a handle assembly 600 together with the spool 667a for controlling the operation of the end effector assembly. By this arrangement, the deflection of the control shaft may be independently operated by the additional spool 667b. While FIG. 10A shows the additional spool 667b disposed distal to the spool 667a, it may also be positioned proximal to the spool 667a, as shown in FIG. 10B. Alternatively, the spools 667a and 667b may be configured and positioned along the main body of the handle assembly 600, as shown in FIG. 10C, so that the spools may slide past one another. The spools shown in the FIG. 10C embodiment are of a hemispheric shape to permit translation past one another. The handle assemblies 600, 600', 600" shown in FIGS. 10A-10C may include suitable locking and/or stopping mechanisms, such as, for example, a locking slot, a stopper, or any other mechanism known in the art.

[0073] In operation, once the distal portion 48 is deflected, the deflection control member 71 may be used to hold the distal portion 48 in the deflected position by actuating or locking the deflection controller 667b. Alternatively, the deflection control member 71 may independently control the deflection of the distal portion 48 by a suitable, separately arranged deflection controller. The deflection control member 71 may then be actuated, independent from the control member 70, so as to deflect, hold, and/or straighten the distal portion 48 of the control shaft 40. For this purpose, a distal end of the deflection control member 71 may be connected to a portion of the distal portion 48. Other operational aspects of these exemplary embodiments may be similar to the exemplary embodiment described with reference to FIGS. 14-18.

[0074] In still another exemplary embodiment of the invention, the wire coil 45 may be provided with a jacket 80 covering at least a portion of the outer surface of the wire coil 45 in the region other than the distal portion 48 intended to be deflected, as shown in FIG. 9. The jacket may create an additional stiffness in the covered region, rendering the uncovered distal portion 48 relatively more flexible than the covered proximal region. Jacketing the wire coil 45 may also allow the deflection of the distal portion 48 without modifying the coil in the distal portion 48. In an exemplary embodiment, the jacket may be made of a polymer material, such as, for example, PTFE, PP, PE, Nylon, Pebax, Polyimide, or any other suitable material.

[0075] In another exemplary embodiment, the distal portion 48 of the wire coil 45 may also be provided with another